Exhibit 300: Capital Asset Plan and Business Case Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview (All Capital Assets)

1. Date of Submission: 2010-03-17 14:08:27

2. Agency: 009

3. Bureau: 10

4. Name of this Investment: FDA Automated Laboratory Management

5. Unique Project (Investment) Identifier: 009-10-01-03-01-8013-00

6. What kind of investment will this be in FY 2011?: Mixed Life Cycle

- Planning
- Full Acquisition
- Operations and Maintenance
- Mixed Life Cycle
- Multi-Agency Collaboration

7. What was the first budget year this investment was submitted to OMB? *

8. Provide a brief summary and justification for this investment, including a brief description of how this closes in part or in whole an identified agency performance gap; this description may include links to relevant information which should include relevant GAO reports, and links to relevant findings of independent audits.

Automated Laboratory Management (ALM) is a program and a portfolio that encompasses eLEXNET, NEIS, LIMS, LabSAN, and QMIS. The Electronic Laboratory Exchange Network (eLEXNET) allows the exchange of laboratory analysis data between over 100 public health labs at the Federal, state, and local levels. The National Biosurveillance Integration System and Electronic Laboratory Exchange Network (NEIS) is an interface with the DHS National Bio-surveillance Integration System. The Laboratory Information Management System (LIMS) is a COTS based solution for managing laboratories. LasSAN and associated hardware provides a storage area network and interface devices for the labs. The Quality Management Information System (QMIS) supports labs and ORA in general in defining, tracking, understanding, and continually improving processes and methods. ALM covers all FDA laboratories, not just those in ORA. ALM is a key FDA program working to improve the efficiency of the staff at FDA laboratories, the quality and quantity of the information the labs provide, and the ability of FDA to share and assess information from and with its own centers, third party, and other public health labs. ALM goals include improving analytical, data mining, and reporting capabilities in eLEXNET and NEIS. LabSAN and associated hardware provide the infrastructure to support meeting ISO/IEC 17025; 1000(E) requirements. LIMS will enable FDA labs to improve chain-of custody tracking, including assignments and sample status; automate collection and processing of analytical data; and track calibration and scheduling to improve the quality of the data produced. QMIS will support document control, corrective actions, complaints, record control, management review, audits, handling of nonconformance, preventive action, and continuous improvement. Ultimately, the ALM program will expand FDA's scientific and research capabilities and improve FDA's ability to share the results of that research with federal, state, local, and international officials and agencies, facilitating improved management of risks associated with FDA-regulated products.

a. **Provide here the date of any approved rebaselining within the past year, the date for the most recent (or planned)alternatives analysis for this investment, and whether this investment has a risk management plan and risk register.**

9. Did the Agency's Executive/Investment Committee approve this request? *

a. **If "yes," what was the date of this approval?** *

10. Contact information of Program/Project Manager?

- **Name:** *
- **Phone Number:** *
- **Email:** *

11. What project management qualifications does the Project Manager have? (per FAC-P/PM)? *

- Project manager has been validated according to FAC-PMPM or DAWIA criteria as qualified for this investment.
- Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.
- Project manager assigned to investment, but does not meet requirements according to FAC-P/OM or DAWIA criteria.
- Project manager assigned but qualification status review has not yet started.
- No project manager has yet been assigned to this investment.

12. If this investment is a financial management system, then please fill out the following as reported in the most recent financial systems inventory (FMSI):

Financial management system name(s)	System acronym	Unique Project Identifier (UPI) number
*	*	*

a. **If this investment is a financial management system AND the investment is part of the core financial system then select the primary FFMIA compliance area that this investment addresses (choose only one):** *

- computer system security requirement;
- internal control system requirement;
- core financial system requirement according to FSIO standards;
- Federal accounting standard;
- U.S. Government Standard General Ledger at the Transaction Level;
- this is a core financial system, but does not address a FFMIA compliance area;
- Not a core financial system; does not need to comply with FFMIA

Section B: Summary of Funding (Budget Authority for Capital Assets)

1.

Table 1: SUMMARY OF FUNDING FOR PROJECT PHASES (REPORTED IN MILLIONS)
(Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)

	PY1 and earlier	PY 2009	CY 2010	BY 2011	BY+1 2012	BY+2 2013	BY+3 2014	BY+4 and beyond	Total
Planning:	*	*	*	*	*	*	*	*	*
Acquisition:	*	*	*	*	*	*	*	*	*
Subtotal Planning & Acquisition:	*	*	*	*	*	*	*	*	*
Operations & Maintenance:	*	*	*	*	*	*	*	*	*
Disposition Costs (optional):	*	*	*	*	*	*	*	*	*
SUBTOTAL:	*	*	*	*	*	*	*	*	*
Government FTE Costs should not be included in the amounts provided above.									
Government FTE Costs	*	*	*	*	*	*	*	*	*
Number of FTE represented by Costs:	*	*	*	*	*	*	*	*	*
TOTAL(including FTE costs)	*	*	*	*	*	*	*	*	*

2. If the summary of funding has changed from the FY 2010 President's Budget request, briefly explain those changes:

*

Section C: Acquisition/Contract Strategy (All Capital Assets)

1.

Table 1: Contracts/Task Orders Table

Contract or Task Order Number	Type of Contract/Task Order (In accordance with FAR Part 16)	Has the contract been awarded (Y/N)	If so what is the date of the award? If not, what is the planned award date?	Start date of Contract/Task Order	End date of Contract/Task Order	Total Value of Contract/Task Order (M)	Is this an Interagency Acquisition? (Y/N)	Is it performance based? (Y/N)	Competitively awarded? (Y/N)	What, if any, alternative financing option is being used? (ESPC, UESC, EUL, N/A)	Is EVM in the contract? (Y/N)
HHSF223200550056W/C-2393	CPFF: Cost Plus Fixed Fee	Y	2005-03-27	2005-03-27	2010-03-26	$8.3	*	*	*	*	*
HHSN31600022	CPFF: Cost Plus Fixed Fee	Y	2008-09-30	2008-09-30	2010-09-29	$1.5	*	*	*	*	*
HHSF223200950016C	FFP, LOE: Firm Fixed Price, Level of Effort Term	Y	2009-09-17	2009-10-09	2010-04-09	$0.5	*	*	*	*	*
HHSF223200950013C	FFP: Firm Fixed Price	Y	2009-09-17	2009-10-14	2014-10-14	$3.5	*	*	*	*	*
HHSF223200950046W	FFP: Firm Fixed Price	Y	2009-08-19	2009-08-19	2009-09-18	$0.0	*	*	*	*	*
HHSF223200950049W	FFP: Firm Fixed Price	Y	2009-08-21	2009-08-21	2009-09-20	$0.2	*	*	*	*	*
HHSF223200950057W	FFP: Firm Fixed Price	Y	2009-09-02	2009-09-02	2009-10-02	$0.1	*	*	*	*	*
HHSF223200950050W	FFP: Firm Fixed Price	Y	2009-08-20	2009-08-20	2009-11-20	$0.1	*	*	*	*	*
eLEXNET and NEIS	FFP: Firm Fixed Price	Y	2010-07-22	2010-08-02	2014-09-30	$14.4	*	*	*	*	*

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:
*

3. Is there an acquisition plan which reflects the requirements of FAR Subpart 7.1 and has been approved in accordance with agency requirements? *

a. **If "yes," what is the date?** *

Section D: Performance Information (All Capital Assets)

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
2006	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	percentage of time where completion of laboratory test and submission of results to elexnet's data entry module is more than 3 days. outcome: more current elexnet data for sharing to be leveraged for protection. measured annually.	59% of data entry laboratories wait more than 3 days to enter laboratory test result data into elexnet.	50% of data entry laboratories wait more than 3 days to enter laboratory test result data into elexnet.	success. in fy06, 37% of data entry laboratories entered data more than 3 days (on average) after the final result date.
2006	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of satisfactory elexnet user experiences, as reported within web-based survey. outcome: improved user experience results in better protection. measured continually.	as of july 2003, user satisfaction is not measured.	improved user satisfaction over baseline percentage, to be measured after web-based survey is implemented.	success. as an alternative to a web-based survey, user satisfaction is monitored via help desk calls. a user satisfaction survey was developed in the 4th quarter of fy 07.
2006	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of concrete examples where accessing information in elexnet prevents foodborne illness. outcome: increased public protection. measured annually.	1 concrete example	10-15 documented examples, based on user feedback, of how the data available in elexnet is used to prevent foodborne illness.	success. 12 concrete examples. data captured in elexnet was used in the food safety and food defense activities. these activities are designed to prevent food borne illness.
2006	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of laboratories actively exchanging data with elexnet. outcome: leverage of laboratory resources to expand protection capability	assuming fy 2004 performance goals are met, 105 laboratories will be actively exchanging data.	expand laboratory participation in elexnet to include 105 laboratories actively exchanging data.	success. exceeded target by two labs, 107 labs were exchanging data by 9/30/06
2006	S.O. 2.2 - Protect the public against injuries and	*	*	number of analytes and select agents routinely tested	0 analytes and select agents	10 analytes and select agents	success. automated reporting of analyte data to

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
	environmental threats			and evaluated using pattern detecting algorithms and/or other data analysis mechanisms. outcome: improved automation to leverage resources for protection. measured continuously as operational			dfs is in place. human review and evaluation of patterns and trends are in process.
2007	Effective Management of Human Capital/Information Technology/Resources	*	*	number of hours the system is down. outcome: greater system availability. measured annually.	12 hours of unplanned downtime	10 hours of unplanned downtime	success. 1 hour of unplanned downtime
2007	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of workflows available through the user interface. outcome: decrease in time to wait for an analysis to start and allows for balancing work between labs and individuals. measured quarterly	0 workflows	1 workflow	success. implemented business process management for food emergency response network interface.
2008	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of analytes and select agents routinely tested and evaluated using pattern detecting algorithms and/or other data analysis mechanisms. outcome: improved automation to leverage resources for protection. measured continuously as operational	10 analytes and select agents	300 analytes and select agents	success. all analytes and select agents (352)
2008	Effective Management of Human Capital/Information Technology/Res	*	*	number of hours the system is down. outcome: greater system availability.	10 hours of unplanned downtime	9 hours of unplanned downtime	success. 4 hours of unplanned downtime

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
	ources			measured annually.			
2008	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of workflows available through the user interface. outcome: decrease in time to wait for an analysis to start and allows for balancing work between labs and individuals. measured quarterly	1 workflow	2 workflows	failure. 1 workflow available. second workflow expected february, 2009
2008	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of labs equipped with labsan servers. outcome: improved managing of equipment maintenance and data backup. measured annually.	0% of labs have labsan servers	100% of labs have labsan servers	success. 100% of labs have labsan servers
2008	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of standardized labsan servers for all ora labs. outcome: improved data sharing and transfer, reduced maintenance for geographically dispersed locations, and leverage of best practices. measured annually.	0 servers	8 servers	success. 9 servers
2008	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of labsan installations with field interconnectivity . outcome: improved availability of data, methods, and equipment status. results in reduced time for emergency response. measured annually.	0 installations	8 installations	failure. 2 installations
2008	S.O. 2.2 - Protect the public against	*	*	% of user requirements accomplished	0% of portal user requirements	10% of portal user requirements	success. 10% of portal user requirements

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
	injuries and environmental threats			for portal configuration. outcome: increased user satisfaction and system usage which reduces the use of telephone, etc. this results in greater staff efficiency. measured annually			accomplished
2009	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of workflows available through the user interface for elexnet. outcome: decrease in time to wait for an analysis to start and allows for balancing work between labs and individuals. measured quarterly	1 workflow for elexnet	2 workflows for elexnet	success. 2 workflows for elexnet
2009	Effective Management of Human Capital/Information Technology/Resources	*	*	number of hours the system is down for elexnet. outcome: greater system availability. measured annually.	9 hours unplanned downtime for elexnet	6 hours unplanned downtime for elexnet	success. 3 hours of unplanned downtime
2009	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of standard reports with map for neis. outcome: allows a visual correlation of events using geospatial data to support trend identification and analysis. measured annually	0 standard reports with map for neis	1 standard report with map for neis	success. 1 standard report with map for neis
2009	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of user requirements accomplished for portal configuration for elexnet. outcome: increased user satisfaction and system usage which reduces the use of telephone, etc.	10% of portal user requirements for elexnet	25% of portal user requirements for elexnet	success. 25% of portal user requirements for elexnet

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
				measured annually			
2009	Effective Management of Human Capital/Information Technology/Resources	*	*	% of hardware installed for labsan in elexnet. outcome: enhanced data collection of instrument data and improved data quality and accountability. measured annually	0% of hardware for elexnet	60% of hardware for elexnet	success. 60% of hardware for elexnet
2009	Effective Management of Human Capital/Information Technology/Resources	*	*	additional gb of data on-line for labsan. outcome: greater data access to support protection. measured annually.	0 gb for ora	500 gb for ora	success. 500 gb for ora
2010	Effective Management of Human Capital/Information Technology/Resources	*	*	% ora employees access to quality system for doc control, corrective actions, complaints, record control, mgmt review, audits, nonconformance, preventive action, cont improvement. outcome: quality emphasized in everyday activities.	0 % of ora employees access to quality management information system	95 % of ora employees access to quality management information system	tbd
2010	Effective Management of Human Capital/Information Technology/Resources	*	*	% of ora labs that are bar code enabled. outcome: automation of tracking samples, etc. measured annually.	0% of ora labs are bar code enabled	100% of ora labs are bar code enabled	tbd
2010	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	error rate percentage of sample identification when logging samples for ora labs. outcome: better sample identification and tracking resulting in better and faster corrective	5% error rate for ora	0.5% error rate for ora	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
				actions via edc. measured annually			
2010	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of workflows available through the user interface for elexnet. outcome: decrease in time to wait for an analysis to start and allows for balancing work between labs and individuals. measured quarterly	2 workflows for elexnet	4 workflows for elexnet	tbd
2010	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of user requirements accomplished for portal configuration for elexnet. outcome: increased user satisfaction and system usage which reduces the use of telephone, etc. this results in greater staff efficiency. measured annually	25% of portal user requirements for elexnet	50% of portal user requirements for elexnet	tbd
2010	Effective Management of Human Capital/Information Technology/Resources	*	*	additional gb of data on-line for labsan. outcome: greater data access to support protection and regulatory compliance. measured annually.	500 gb for labsan	2 tb for labsan	tbd
2010	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of new functions for ora to improve scientific research to help safeguard the public. outcome: standardization and refinement of workflows through specific functions of different groups. measured annually	0% of new functions for ora	100% of new functions for ora	tbd
2010	S.O. 2.2 -	*	*	duplicative	minimum 2	single on-line	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
	Protect the public against injuries and environmental threats			result entry for ora. outcome: reduction in ftes required to perform this function and a reduction in errors. measured annually	times using hard copy, often 3 times for ora	entry for ora	
2010	Effective Management of Human Capital/Information Technology/Resources	*	*	% of hardware installed for labsan for ora. outcome: enhanced data collection of instrument data and improved data quality and accountability. measured annually	60% of hardware for ora	100% of hardware for ora	tbd
2011	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of ora labs and district offices with consistent and well-defined national quality factors. outcome: defined, accepted, universal culture of quality with reduced errors.	0 % of ora labs and district offices	95 % of ora labs and district offices	tbd
2011	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of ora labs with lims functionality. outcome: improved tracking of inventory (such as reagents) and equipment calibration, resulting in cost savings. provides equipment calibration, records for legal actions. measured annually	0 ora labs with lims functionality	1 ora lab with lims functionality	tbd
2011	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% reduction in reporting time from laboratory to stakeholders for ora. outcome: faster corrective actions. measured annually	0% for ora labs	10% for ora labs	tbd
2011	S.O. 2.2 - Protect the	*	*	number of standardized	0 standardized data exchange	1 standardized data exchange	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
	public against injuries and environmental threats			data exchange services for elexnet. outcome: increased level of laboratory participation in automated data exchange . measured annually	services	service	
2012	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% improvement in consistent and uniform quality products and process (quality in conjunction with ora lab management). outcome: improvement in consistently valid results.	0 % improvement for ora	20% improvement for ora	tbd
2012	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of ora labs with lims functionality. outcome: improved tracking of inventory (such as reagents) and equipment calibration, resulting in cost savings. provides equipment calibration, records for legal actions. measured annually	1 ora lab with lims functionality	13 ora labs with lims functionality	tbd
2012	Effective Management of Human Capital/Information Technology/Resources	*	*	number of hours of operational downtime for maintenance for ora and center labs. outcome: greater system availability. measured annually	60 hours for ora and center labs	45 hours for ora and center labs	tbd
2012	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of labs converted from manual to automated data entry into elexnet. outcome: reduction in fte time required and improved response to changing conditions to	30% of labs	50% of labs	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
				support protection. measured annually			
2012	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of interoperating ora laboratories. outcome: software interoperation to improve data exchange and communication. measured annually	0 ora laboratories	1 ora laboratory	tbd
2012	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% increase in use because of improved system performance to accommodate an increase in the number of system users. outcome: real-time collaboration. measured annually	0% increase in use	10% increase in use	tbd
2012	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of ora systems consolidated to provide full access to data to support regulatory decisions. outcome: improved compliance officer productivity. measured annually	0% of ora systems	20% of ora systems	tbd
2012	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of ora laboratories with a mechanism for read only access to non-laboratory users with some reporting capabilities. outcome: improved information sharing and access for fda (investigations) and non-fda (states) groups. measured annually	0 ora laboratories	5 ora laboratories	tbd
2013	S.O. 2.2 - Protect the public against	*	*	% of ora labs with software workflow.	0% of ora labs have software workflow	100% of ora labs have software	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
	injuries and environmental threats			outcome: reduced time needed to analyze and report on samples. fast status reporting for compliance functions. measured annually		workflow	
2013	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of analytical processes controlled by software for ora. outcome: reduction in data entry errors. measured quarterly	0% of analytical processes are software controlled for ora	50% of analytical processes are software controlled for ora	tbd
2013	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of interoperating ora laboratories. outcome: software interoperation to improve data exchange and communication. measured annually	1 ora laboratory	5 ora laboratories	tbd
2013	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% increase in use because of improved system performance to accommodate an increase in the number of system users. outcome: real-time collaboration. measured annually	10% increase in use	20% increase in use	tbd
2013	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of ora systems consolidated to provide full access to data to support regulatory decisions. outcome: improved compliance officer productivity. measured annually	20% of ora systems	50% of ora systems	tbd
2013	S.O. 2.2 - Protect the public against injuries and environmental	*	*	number of ora laboratories with a mechanism for read only access to	5 ora laboratories	10 ora laboratories	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
	threats			non-laboratory users with some reporting capabilities. outcome: improved information sharing and access for fda (investigations) and non-fda (states) groups. measured annually			
2014	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of interoperating ora laboratories. outcome: software interoperation to improve data exchange and communication. measured annually	5 ora laboratories	10 ora laboratories	tbd
2014	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% increase in use because of improved system performance to accommodate an increase in the number of system users. outcome: real-time collaboration. measured annually	20% increase in use	25% increase in use	tbd
2014	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of ora systems consolidated to provide full access to data to support regulatory decisions. outcome: improved compliance officer productivity. measured annually	50% of ora systems	100% of ora systems	tbd
2014	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	number of ora laboratories with a mechanism for read only access to non-laboratory users with some reporting capabilities. outcome: improved information	10 ora laboratories	13 ora laboratories	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
				sharing and access for fda (investigations) and non-fda (states) groups. measured annually			
2014	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of center labs with lims functionality. outcome: improved tracking of inventory (such as reagents) and equipment calibration, resulting in cost savings. provides equipment calibration, records for legal actions. measured annually	0% of center labs with lims functionality	100% of center labs with lims functionality	tbd
2014	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of analytical processes controlled by software for ora. outcome: reduction in data entry errors. measured quarterly	50% of analytical processes are software controlled for ora	100% of analytical processes are software controlled for ora	tbd
2014	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of center labs with software workflow. outcome: reduced time needed to analyze and report on samples. fast status reporting for compliance functions. measured annually	0% of center labs have software workflow	100% of fda labs have software workflow	tbd

Part II: Planning, Acquisition And Performance Information

Section A: Cost and Schedule Performance (All Capital Assets)

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline

Description of Milestones	Planned Cost ($M)	Actual Cost ($M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
COMPLETED ALM DME: Version 1 - Pilot Project - analysis, design, delivery, Version 2, Version 3.0, Version 4.0, HL-7 Development, HL-7 Development, NBIS Requirements and Design, Methods Module SOA, NBIS Development, Test and Implementation	$11.1	$11.1	1999-09-03	1999-09-03	2009-03-27	2009-03-27	100.00%	100.00%
electronic Laboratory Exchange Network (eLEXNET) 2: ALBPM, Portal Enhancement, Integrate eLEXTNET and DX Labs, Geospatial Information Services, Integrate eLEXNET and Electronic Data Capture, eLEXNET Method Module, eLEXNET and FoodShield/FERN Lab	$1.7	$1.5	2008-03-28	2008-03-28	2010-03-27	2010-03-27	100.00%	100.00%
electronic Laboratory Exchange Network (eLEXNET) 3: Portal update. Web services. Method module review process. New formats such as HTML, etc.	$3.2	$0.3	2010-03-28	2010-03-28	2012-03-27		11.97%	11.00%

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline

Description of Milestones	Planned Cost ($M)	Actual Cost ($M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Conversion of excel files to XML. GIS integration. Custom interfaces for each non-FDA lab								
electronic Laboratory Exchange Network (eLEXNET) 4: Increased types and number of analytes. Two-way communications integration. Internationalization. Portal update. Strategic Communications. Private and academic laboratory data.	*	*	2012-03-28		2014-09-30		0.00%	0.00%
National Biosurveillance Integration System and Electronic Laboratory Exchange Network (NEIS): Daily Feed Messaging Support, User Interface Redesign, Prototype Time Series Support, Enhanced Auditing, Logging, and Security Tracking, Mapping Interface	$0.8	$1.1	2008-10-01	2008-10-01	2010-09-30		85.43%	65.34%
Electronic Data Capture (EDC): Forms for electronic data entry, Laboratory automation analysis, data capture for specific laboratory processes. Includes 0.300 FY09	$3.1	$0.2	2009-07-01	2009-08-17	2010-09-30		4.94%	5.30%

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline

Description of Milestones	Planned Cost ($M)	Actual Cost ($M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
(35M)								
High Throughput Management (HTM): Software implementation in ORA laboratories. Automated management of biological and chemical laboratory processes, Software implementation in FDA laboratories. Automated management for additional workflow processes	$5.3	$0.2	2009-10-01	2009-10-09	2011-09-30		3.12%	3.10%
Laboratory Information Management System (LIMS) 1: Software implementation in ORA laboratories, Software implementation in FDA laboratories. Management of individual workflows and processes. Optimization of processes and statistical analysis	$5.6	$0.2	2009-10-01	2009-10-09	2011-09-30		2.98%	3.10%
Laboratory Information Management System (LIMS) 2: Additional workflows and processes, continued optimization	*	*	2011-10-01		2013-09-30		0.00%	0.00%
Laboratory Hardware 1: Laptops, tablet PCs, bar code scanners, file and	$2.0	$1.4	2009-07-01	2009-08-17	2010-09-30		70.00%	70.00%

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline

Description of Milestones	Planned Cost ($M)	Actual Cost ($M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
application servers, printers, wiring, etc. FY08								
Laboratory Hardware 2: Laboratory Hardware Improvement	*	*	2010-10-01		2012-09-30		0.00%	0.00%
Laboratory Hardware 3: Laboratory Hardware Improvement	*	*	2012-10-01		2014-09-30		0.00%	0.00%
Quality Management Information System (QMIS) 1: Document Control Procedure, Corrective Action Procedure, Feedback and Complaint Procedure, Audit Procedure, Record Control Procedure, Control of Nonconformance Procedure, Preventive Action Procedure	$0.9	$0.4	2009-07-01	2009-10-14	2011-06-30		55.58%	48.98%
Quality Management Information System (QMIS) 2: Integration with Investigations and Compliance, Master Document List, Metadata for Linked Documents, Single Sign On	*	*	2011-07-01		2013-09-30		0.00%	0.00%
Management Reserve: Funds in reserve to	$0.5	$0.1	2009-10-01	2010-07-07	2014-09-30		13.00%	15.00%

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline

Description of Milestones	Planned Cost ($M)	Actual Cost ($M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
deal with								
Security: FDA FTEs, contractors, POA&M, C&A	$2.9	$0.4	2008-10-01	2008-10-01	2014-09-30		23.02%	15.65%
EA CPIC: FDA FTEs, contractors, CPIC, E-300, EVM, EA	$1.6	$0.4	2008-10-01	2008-10-01	2014-09-30		38.25%	29.18%
Program Management: FDA FTEs, contractors, program management, project management, EPLC, scheduling, tracking, planning	$4.7	$1.0	2008-10-01	2008-10-01	2014-09-30		31.77%	24.13%
COMPLETED ALM SS: Version 2.1, Version 2.5, Version 3.1, Version 3.2, Expansion of Laboratories (FY05 PART Goal), Expansion of Laboratories (FY06 PART Goal), Maintenance/ Operations FY04, Maintenance/ Operations FY05, Maintenance/ Operations FY06	$12.0	$12.0	2001-06-05	2001-06-05	2008-09-30	2008-09-30	100.00%	100.00%
SS Operations FY09	$0.9	$0.8	2008-10-01	2008-10-01	2009-09-30	2009-09-30	100.00%	100.00%
SS Operations FY10	$2.5	$0.4	2009-10-01	2009-10-01	2010-09-30		71.74%	40.00%
SS Operations FY11	*	*	2010-10-01		2011-09-30		0.00%	0.00%
SS Operations FY12	*	*	2011-10-01		2012-09-30		0.00%	0.00%
SS Operations	*	*	2012-10-01		2013-09-30		0.00%	0.00%

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline								
Description of Milestones	Planned Cost ($M)	Actual Cost ($M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
FY13								
SS Operations FY14	*	*	2013-10-01		2014-09-30		0.00%	0.00%

* - Indicates data is redacted.